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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,920

01/25/2006

Sanjay E. Rastogi

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NIXON & VANDERHYE, PC  
901 NORTH GLEBE ROAD, 11TH FLOOR  
ARLINGTON, VA 22203

EXAMINER

CHOI, LING SIU

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

07/11/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/561,920	<b>Applicant(s)</b> RASTOGI ET AL.	
	<b>Examiner</b> Ling-Siu Choi	<b>Art Unit</b> 1796	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 06 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/06/2008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. This Office Action is in response to the Amendment filed 03/06/2008. Claims 12-14 were canceled and claims 1-11 are now pending. The claim rejections under USC § 102(b)/103(a) over Burstein et al. (US 5,721,334) and Rastogi et al. (US 6,433,120) are maintained.

### *Claim Analysis*

2. Summary of Claim 1:

Process to prepare a shaped part of an ultrahigh molecular weight polyethylene (UHMWPE)	
<ul style="list-style-type: none"><li>- heating the UHMWPE to a temperature above the melting temperature,</li><li>- shaping the resulting melt, and</li><li>- cooling the melt to a temperature below the melting temperature, wherein</li></ul>	
A	the UHMWPE has a weight average molecular weight (Mw) of at least $1 \times 10^6$ g/mol
B	during the shaping the storage plateau modulus ( $G^*$ ) of the UHMWPE is kept at a value of at most 1.5 MPa
C	whereafter, before the cooling, the $G^*$ is raised to its final value

### *Claim Rejections - 35 USC § 102/103*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office

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**action:**

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-11 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Burstein et al. (US 5,721,334).

Burstein et al. disclose a process to make a shaped article, the process comprising (a) filling a mold with powdered ultra high molecular weight polyethylene; (b) raising the temperature of the mold to between about 140-225°C while simultaneously applying a pressure of between about 2.5 -15 MPa to the mold and its contents; (c) maintaining the pressure and temperature for between about 5 -25 min to allow the mold contents to equilibrate at the selected temperature; and (d) dropping the temperature of the molded part at a rate between about 4 -175°C./min by contact with a suitable cooling fluid such as water or air, wherein the ultra high molecular weight polyethylene (UHMWPE) has an average molecular weight of between about 1 x 10<sup>6</sup> and about 10 x 10<sup>6</sup>; the shaped article so produced exhibits a combination of properties

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including an elastic modules between about 500- 800 MPa, a yield strength  $\geq$  about 20 MPa, an elongation to rupture  $>$  about 300%, crystallinity and density  $\leq$  the native powdered UHMWPE; and the shaped articles are used in the bearing surface of total knee joints, prosthetic hip joint cups, and other prosthetic shapes for replacement of other joints of the human body (abstract; claim 1). However, Burstein et al. are silent on the specific properties in the shaping stage. In view of the process and the UHMWPE being substantially identical to the corresponding ones of the present claims, the shaped article would possess the claimed properties of the shaping stage because such claimed properties mainly depend on the molecular weight of UHMWPE and the processing conditions. Since PTO does not have proper means to conduct experiments, the burden of proof is now shifted to applicants to show otherwise. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977); *In re Fitzgerald* 205 USPQ 594 (CCPA 1980).

6. Claims 1-11 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rastogi et al. (US 6,433,120 B1).

Rastogi et al. disclose a process to process ultra-high molecular weight polyethylene (UHMWPE) having a molecular weight (Mw) of at least 400,000, the process comprising (a) providing UHMWPE particles having a lamellar thickness of  $<12$  nm and a melting temperature at atmospheric pressure  $>141^{\circ}$  C; (b) heating the particles from ambient temperature under an elevated pressure of at least 0.5 kbar in a pressure cell; (c) continuing the heating of the resulting UHMWPE under an elevated pressure to at least the melting temperature of the UHMWPE; (d) cooling the resulting

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melted UHMWPE product to ambient temperature; and (e) removing the cooled product from the pressure cell, wherein the speed of heating in step (c) is 0.5-5°C./min (claim 1 and 13). However, Rastogi et al. are silent on the specific properties in the shaping stage. In view of the process and the UHMWPE being substantially identical to the corresponding ones of the present claims, the shaped article would possess the claimed properties of the shaping stage because such claimed properties mainly depend on the molecular weight of UHMWPE and the processing conditions. Since PTO does not have proper means to conduct experiments, the burden of proof is now shifted to applicants to show otherwise. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977); *In re Fitzgerald* 205 USPQ 594 (CCPA 1980).

### ***Response to Arguments***

7. Applicant's arguments filed 03/06/2008 have been fully considered but they are not persuasive.

In view of the Amendment, it is informed that the UHMWPE used in the disclosure of Burstein et al. and Rastogi et al. is 415 GUR resin which is available from Hoechst Celanese and is an entangled UHMWPE. As such, the storage plateau modulus ( $G^*$ ) of the UHMWPE used in the disclosure of Burstein et al. and Rastogi et al. can not be kept at most 1.5 MPa during the shaping process. If it is the case, the claim rejections over Burstein et al. or Rastogi et al. will be withdrawn. Thus, a declaration is sought.

***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ling-Siu Choi whose telephone number is 571-272-1098.

If attempt to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu, can be reached on 571-272-1114.

/Ling-Siu Choi/

Primary Examiner, Art Unit 1796

June 30, 2008

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